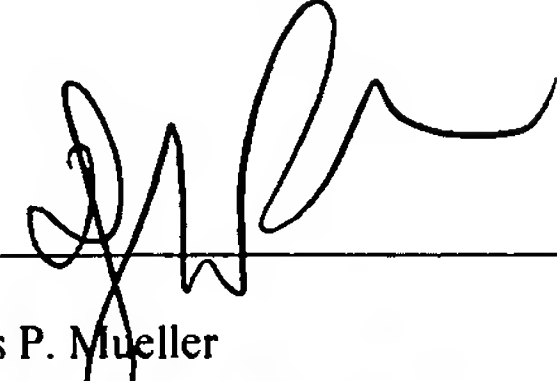


|   |   |   |  |
|---|---|---|--|
| FORM PTO-1390<br>(REV 10-94)  |   | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTORNEY'S DOCKET NUMBER<br>10873.1788USWO                                   |
| TRANSMITTAL LETTER TO THE UNITED STATES<br>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br>CONCERNING A FILING UNDER 35 U.S.C. 371  |   |   | U.S. APPLICATION NO. (If known, see 37 CFR 1.51)<br>Unknown <b>10/551898</b> |
| INTERNATIONAL APPLICATION NO.<br>PCT/JP2004/003836  | INTERNATIONAL FILING DATE<br>March 22, 2004 | PRIORITY DATE CLAIMED<br>April 4, 2003                  |  |
| TITLE OF INVENTION<br>MEDICAL NEEDLE DEVICE WITH WINGED SHIELD (AS AMENDED)   |   |   |  |
| APPLICANT(S) FOR DO/EO/US<br>MORIWAKI et al.  |   |   |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |   |   |  |
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).</li> <li>4. <input type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been transmitted by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)</li> </ol> </li> <li>6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input type="checkbox"/> have been transmitted by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An unsigned oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).</li> <li>10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> |   |   |  |
| <b>Items 11. to 16. below concern document(s) or information included:</b>  |   |   |  |
| 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98, Form 1449, references.   |   |   |  |
| 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.  |   |   |  |
| 13. <input checked="" type="checkbox"/> A FIRST preliminary amendment.<br><input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.  |   |   |  |
| 14. <input type="checkbox"/> A substitute specification.  |   |   |  |
| 15. <input type="checkbox"/> A change of power of attorney and/or address letter.   |   |   |  |
| 16. <input checked="" type="checkbox"/> Other items or information: Application Data Sheet (5 pages), 5 sheets of formal drawings, Communication regarding Figure Publication, International Publication Page WO 2004/089449 A1, Form PCT/ISA/210, Form PCT/IB/304, Form PCT/IB/308, Form PCT/ISA/237   |   |   |  |

1020 Rec'd PCT/PTO 04 OCT 2005

|   |              |  |         |                          |   |
|---|--------------|--|---------|--------------------------|---|
| U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)  |              | INTERNATIONAL APPLICATION NO.                                    |         | ATTORNEY'S DOCKET NUMBER |   |
| Unknown <b>10/551898</b>  |              | PCT/JP2004/003836  |         | 10873.1788USWO           |   |
| <b>BASIC NATIONAL FEE (37 CFR 1.492(a) (1)-(5)):</b>  |              |  |         |                          |   |
| [X] a) Basic National fee.....\$300   |              |  |         | \$300                    |   |
| [X] b) Examination fee.....\$200  |              |  |         | \$200                    |   |
| [X] c) Search fee.....\$500   |              |  |         | \$500                    |   |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |              |  |         | <b>\$1000</b>            |   |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. |              |  |         |                          |   |
| Total Sheets  | Extra Sheets | Number of each additional set of 50 sheets, more than 100 sheets | Rate    |                          |   |
| 24 -100 =   | 0 /50 =      | 0  | X \$250 | \$0                      |   |
| Surcharge of \$130.00 for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).   |              |  |         | \$0                      |   |
| CLAIMS  | NUMBER FILED | NUMBER EXTRA   | RATE    |                          |   |
| Total claims  | 7 -20 =      | 0  | X \$50  | \$0                      |   |
| Independent claims  | 1 -3 =       | 0  | X \$200 | \$0                      |   |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)   |              |  | + \$360 | \$0                      |   |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |              |  |         | <b>\$1000</b>            |   |
| Reduction by 1/2 for filing by small entity, if applicable. Small entity status is claimed pursuant to 37 CFR 1.27  |              |  |         | \$0                      |   |
| <b>SUBTOTAL =</b>   |              |  |         | <b>\$1000</b>            |   |
| Processing fee of \$130 for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).   |              |  |         | + \$0                    |   |
| <b>TOTAL NATIONAL FEE =</b>   |              |  |         | <b>\$1000</b>            |   |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property  |              |  |         | + \$0                    |   |
| <b>TOTAL FEES ENCLOSED =</b>  |              |  |         | <b>\$1000</b>            |   |
|   |              |  |         | Amount to be: refunded   | \$0   |
|   |              |  |         | charged                  | \$0   |
| a. [X] Check(s) in the amount of \$1000 to cover the above fees is enclosed.  |              |  |         |                          |   |
| b. [ ] Please charge the amount of \$ to cover the required filing fee for a large entity to the credit card listed on the enclosed credit card authorization form.   |              |  |         |                          |   |
| c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-3478.   |              |  |         |                          |   |
| <b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>                                  |              |  |         |                          |   |
| SEND ALL CORRESPONDENCE TO:<br>Douglas P. Mueller<br>Hamre, Schumann, Mueller & Larson, P.C.<br>P.O. Box 2902-0902<br>Minneapolis, MN 55402   |              |  |         |                          |   |
|   |              |  |         | SIGNATURE:               |  |
|   |              |  |         | NAME:                    | Douglas P. Mueller  |
|   |              |  |         | REGISTRATION NUMBER:     | 30,300  |

**10/551898****JC04 Rec'd PCT/PTO 04 OCT 2005****UNITED STATES PATENT AND TRADEMARK OFFICE**

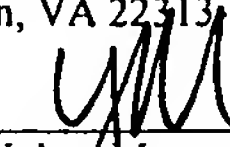
Applicant: MORIWAKI et al.  
Attorney Docket: 10873.1788USWO  
Title: MEDICAL NEEDLE DEVICE WITH WINGED SHIELD (AS AMENDED)

**CERTIFICATE UNDER 37 CFR 1.10**

Express Mail mailing label number: EV 648467955 US

Date of Deposit: October 4, 2005

I hereby certify that the papers listed below are being deposited with the United States Postal Service Express Mail Post Office to Addressee service under 37 CFR 1.10 in an envelope addressed to: Mail Stop Application, Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450.

By:   
Name: Yuhgo Maruta

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**53148**

PATENT TRADEMARK OFFICE

Commissioner:

The following papers are transmitted herewith:

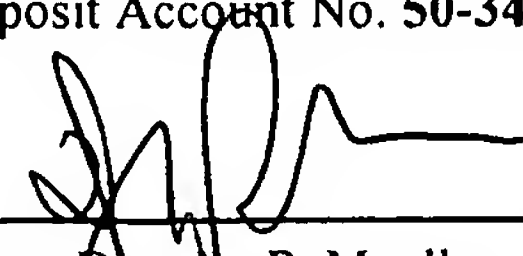
- ☒ Transmittal sheet, in duplicate, containing Certificate Under 37 CFR 1.10;
- ☒ National Stage Patent Application including: Description - 11 pages; 7 Claims - 2 pages; Abstract - 1 page; Drawings - 5 sheets (formal);
- ☒ Unsigned Combined Declaration and Power of Attorney;
- ☒ Application Data Sheet - 5 pages;
- ☒ Other: Preliminary Amendment (5 pages), Form 1390, Communication regarding Figure Publication, International Publication Page WO 2004/089449 A1, Form PCT/ISA/210, Form PCT/IB/304, Form PCT/IB/308, Form PCT/ISA/237
- ☒ Check(s) for the amount of \$1000 to cover the filing fee calculated below;
- ☒ Return postcard

**CLAIMS AS FILED**

| Number of Claims Filed        | No. | In Excess of | Extra | Rate (\$) | Fee (\$) |
|-------------------------------|-----|--------------|-------|-----------|----------|
| Total Claims                  | 7   | 20           | 0     | 50        | 0        |
| Independent Claims            | 1   | 3            | 0     | 200       | 0        |
| Multiple Dependent Claims Fee |     |              |       |           | 0        |
| Basic Filing Fee              |     |              |       |           | 300      |
| Search Fee                    |     |              |       |           | 500      |
| Examination Fee               |     |              |       |           | 200      |
| Utility Application Size Fee  | 24  | 100          | 0     | 250       | 0        |
| Total                         |     |              |       |           | 1000     |

Please charge any additional fees or credit overpayment to Deposit Account No. 50-3478. A duplicate of this sheet is enclosed.

Hamre, Schumann, Mueller & Larson, P.C.  
P.O. Box 2902-0902 Minneapolis, MN 55402  
612.455-3800

By:   
Name: Douglas P. Mueller  
Reg. No.: 30,300  
Initials: DPM/acp

(PTO TRANSMITTAL - NEW FILING)

S/N Unknown

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: MORIWAKI et al. Serial No.: Unknown  
Filed: Concurrent herewith Docket No.: 10873.1788USWO  
Title: MEDICAL NEEDLE DEVICE WITH WINGED SHIELD (AS AMENDED)

CERTIFICATE UNDER 37 CFR 1.10

Express Mail mailing label number: EV 648467955 US

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By:   
Name: Yuhgo Maruta

COMMUNICATION REGARDING REQUESTED FIGURE

Mail Stop PCT  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Dear Commissioner:

In connection with the above-identified application, applicant respectfully requests that Figure 1 be printed on the front page of the published application.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' primary attorney-of record Douglas P. Mueller (Reg. No. 30,300), at (612) 455.3804.

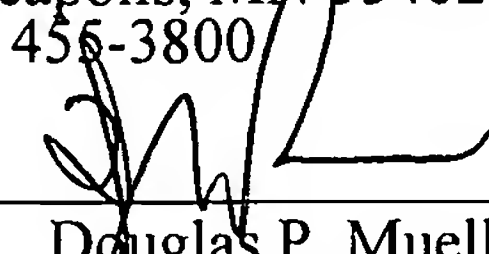
**53148**

PATENT TRADEMARK OFFICE

Dated: October 4, 2005

Respectfully submitted,

HAMRE, SCHUMANN, MUELLER &  
LARSON, P.C.  
P.O. Box 2902-0902  
Minneapolis, MN 55402-0903  
(612) 455-3800

By:   
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Reg. No. 30,300  
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